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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,981

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1794

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,981	<b>Applicant(s)</b> JEMELIN, VINCENT	
	<b>Examiner</b> WALTER B. AUGHENBAUGH	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/06</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Specification***

1. The abstract of the disclosure is objected to because language that can be implied such as “The present invention relates to” (line 1) should be avoided. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sudo (USPN 5,723,189).

In regard to claim 7, Sudo teaches a capsule that corresponds to the claimed capsule that is formed of cyclic olefin copolymer (see, for example, col. 12, lines 28-37 and 57-65 and col. 11, lines 45-48).

In regard to claim 8, Sudo teaches a package that corresponds to the claimed package that comprises a capsule that is formed of cyclic olefin copolymer (see, for example, col. 12, lines 28-37 and 57-65 and col. 11, lines 45-48) and a cap that seals the capsule (see, for example, col. 12, lines 28-37 and Fig. 4).

In regard to claim 9, Sudo teaches a package that corresponds to the claimed package that comprises a capsule that is formed of cyclic olefin copolymer (see, for example, col. 12, lines 28-

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37 and 57-65 and col. 11, lines 45-48) and a barrier that seals the capsule (see, for example, col. 12, lines 28-37 and Fig. 4).

In regard to claim 10, Sudo teaches a package that corresponds to the claimed package that comprises a capsule that is formed of cyclic olefin copolymer (see, for example, col. 12, lines 28-37 and 57-65 and col. 11, lines 45-48), a cap (stopper 9) and an aluminum barrier (layer of aluminum) that seals the capsule (see, for example, col. 12, lines 28-37, col. 12, line 66-col. 13, line 13 and Fig. 4).

4. Claims 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sudo et al. (USPN 5,853,833).

In regard to claim 7, Sudo et al. teach a capsule that corresponds to the claimed capsule that is formed of cyclic olefin copolymer (see, for example, col. 9, lines 10-19, col. 3, lines 40-49 and col. 66, lines 32-34).

In regard to claim 11, Sudo et al. teach that the capsule that corresponds to the claimed capsule that is formed of cyclic olefin copolymer is coated with silicon oxide (see, for example, col. 9, lines 10-17).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sudo (USPN 5,723,189).

Sudo teaches the package as discussed above in regard to claims 7-10.

Sudo fails to explicitly teach an ampoule within the capsule, where the ampoule is formed of cyclic olefin copolymer.

Sudo, however, discloses that it is well known in the art that ampoules containing liquid medicament are enclosed in a container (col. 1, lines 64-66) in order to maintain the sanitary nature of the medicament during storage of the medicament in a container (col. 1, lines 9-17) and that the cyclic olefin copolymer is suitable for use as any of a multiplicity of containers such as cases, sacks, vials, press through packs, slip pouches, partitioned vessels, ampoules “and the like) (col. 12, lines 28-37). Therefore, one of ordinary skill in the art would have recognized to have stored ampoules in the capsule taught by Sudo since it is well known in the art that ampoules containing liquid medicament are enclosed in a container in order to maintain the sanitary nature of the medicament during storage of the medicament in a container as taught by Sudo, and to have used cyclic olefin copolymer as the material of the ampoules since cyclic

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olefin copolymer is a suitable material for use as the material of ampoule used to store medicament as taught by Sudo.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored ampoules in the capsule taught by Sudo since it is well known in the art that ampoules containing liquid medicament are enclosed in a container in order to maintain the sanitary nature of the medicament during storage of the medicament in a container as taught by Sudo, and to have used cyclic olefin copolymer as the material of the ampoules since cyclic olefin copolymer is a suitable material for use as the material of ampoule used to store medicament as taught by Sudo.

7. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sudo (USPN 5,723,189) in view of Sudo et al. (USPN 5,853,833).

Sudo teaches the package as discussed above in regard to claims 7-10. Sudo teaches that the an additional layer of another material may be applied to the surface of the container comprising the cyclic olefin (such as the capsule) (col. 12, lines 57-65 and col. 13, lines 9-13).

Sudo fails to explicitly teach that the capsule is coated with silicon oxide.

Sudo et al. (USPN 5,853,833), however, disclose a sanitary container (see, for example, col. 6, lines 32-34) comprising a cyclic olefin (see, for example, col. 3, lines 40-49) that has a silicon oxide coating applied to the surface of the cyclic olefin container (see, for example, col. 9, lines 10-17) that improves the transmission resistance to oxygen and nitrogen of the cyclic olefin container (see, for example, col. 3, lines 5-19). Therefore, one of ordinary skill in the art would have recognized to have coated the capsule of Sudo with the silicon oxide coating of Sudo

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et al. in order to improve the transmission resistance to oxygen and nitrogen of the cyclic olefin container of Sudo as taught by Sudo et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the capsule of Sudo with the silicon oxide coating of Sudo et al. in order to improve the transmission resistance to oxygen and nitrogen of the cyclic olefin container of Sudo as taught by Sudo et al.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sudo et al. (USPN 5,853,833) in view of Sudo (USPN 5,723,189).

Sudo et al. teach the package as discussed above in regard to claim 11.

Sudo et al. fail to explicitly teach an ampoule within the capsule, where the ampoule is formed of cyclic olefin copolymer.

Sudo (USPN 5,723,189), however, discloses that it is well known in the art that ampoules containing liquid medicament are enclosed in a container (col. 1, lines 64-66) in order to maintain the sanitary nature of the medicament during storage of the medicament in a container (col. 1, lines 9-17) and that the cyclic olefin copolymer is suitable for use as any of a multiplicity of containers such as cases, sacks, vials, press through packs, slip pouches, partitioned vessels, ampoules “and the like) (col. 12, lines 28-37). Therefore, one of ordinary skill in the art would have recognized to have stored ampoules in the capsule taught by Sudo et al. since it is well known in the art that ampoules containing liquid medicament are enclosed in a container in order to maintain the sanitary nature of the medicament during storage of the medicament in a container as taught by Sudo, and to have used cyclic olefin copolymer as the material of the

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ampoules since cyclic olefin copolymer is a suitable material for use as the material of ampoule used to store medicament as taught by Sudo.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored ampoules in the capsule taught by Sudo et al. since it is well known in the art that ampoules containing liquid medicament are enclosed in a container in order to maintain the sanitary nature of the medicament during storage of the medicament in a container as taught by Sudo, and to have used cyclic olefin copolymer as the material of the ampoules since cyclic olefin copolymer is a suitable material for use as the material of ampoule used to store medicament as taught by Sudo.

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris, can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /  
Patent Examiner, Art Unit 1794

3/30/08